

Application No.: 10/743,667  
Amendment Dated: February 11, 2007  
Reply to Office Action Mailed September 11, 2006

## **REMARKS/ARGUMENTS**

Claims 1 through 14 are pending in the instant application. The applicants have amended claim 1, support for which may be found within claim 6, as originally filed, applicants' drawings and elsewhere throughout applicants' specification. Applicants have cancelled claims 2 and 5 through 6 without prejudice or disclaimer of subject matter. The applicants have amended claim 7 to provide proper dependency in view of the cancellation of claim 6.

The Examiner has rejected claims 1 through 4, 8 and 10 through 13 under 35 U.S.C. 102(b) as being anticipated by Kletschka et al., U.S. Patent No. 3,910,281. The Examiner has rejected claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Pierce U.S. Patent No. 4,823,794. The Examiner has rejected claim 5 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Wixey et al., U.S. Publication No. 2005/0096699. The Examiner has rejected claim 9 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Biggs et al., U.S. Patent No. 6,599,311. The Examiner has rejected claim 14 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Lyons et al., U.S. Publication No. 2004/0260344. The rejection of applicants' claims, as amended, is respectfully traversed. Reconsideration and favorable action is respectfully solicited in view of the following comments.

The Examiner has rejected claims 1 through 4, 8 and 10 through 13 under 35 U.S.C. 102(b) as being anticipated by Kletschka et al., U.S. Patent No. 3,910,281. Kletschka et al., U.S. Patent No. 3,910,281, proposes a suture having a surgical needle connectable to one end has an enlarged anchoring member

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secured to the other end thereof. A lateral projection is said to be provided on the anchoring member. It is proposed that the lateral projection be grasped by a physical instrument to position the anchor member during the suture tying procedure and a slit formed in the anchor member is said to releasably secure the suture to the anchor member for subsequent tensioning adjustments. The Examiner is of the view that:

Kletschka teaches a suture anchoring device comprising: a first retaining member (24e) having a first surface, a second surface and a first outer edge; where the second surface lies in a first plane; the first retaining member having an opening (19e) that extends from the first outer edge to an inner point of the first retaining member; a second retaining member (18e) having a third surface, a fourth surface and a second outer edge; where the third surface lies in a second plane, the second retaining member having a holding means (19e); a coupler (23e) having a third outer edge and a cross-sectional area taken in a plane parallel to the first plane that is smaller than the cross-sectional area of the first retaining member taken in a plane parallel to the first plane (fig. 5); where the coupler joins the first retaining member to the second retaining member at the second surface and third surface; wherein the second and third surfaces are parallel to each other and non-coterminous.

A careful review of Kletschka et al. reveals that nowhere does Kletschka et al. disclose a second retaining member having a third surface, a fourth surface, a fifth surface, a sixth surface and a second outer edge; where the third surface lies in a second plane and the fifth surface and the sixth surface lie nominally perpendicular to the second outer edge at their lines of intersection therewith. Moreover, nowhere does Kletschka et al. disclose a holding means positioned within the second retaining member, the holding means comprised of an opening extending from the fifth or the sixth surface to within the second retaining member.

As stated in MPEP § 2131, in order to constitute anticipation under the law, a patent or publication must contain within its four corners a sufficient description to enable the person of ordinary skill to make the invention without undue

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experimentation. All material elements of a claim must be found in one prior art source, a mere suggestion is not enough and essential elements are not to be read into a reference. If a reference does not expressly recite or disclose applicants' claimed invention, as is the case here, then, it is required under principles of inherency that the claimed subject matter be inevitably produced when the teachings of the relied upon reference are followed, in order for a proper case of anticipation to be found.

As such, it is respectfully submitted that applicants' claimed invention is not fairly taught, and that following the teachings of Kletschka et al. would not inevitably produce the invention, as claimed. In view thereof, it is respectfully requested that the grounds for rejection of claims 1 through 4, 8 and 10 through 13 under 35 U.S.C. 102(b) as being anticipated by Kletschka et al., U.S. Patent No. 3,910,281, be removed.

The Examiner has rejected claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Pierce, U.S. Patent No. 4,823,794. As indicated above, Kletschka et al., U.S. Patent No. 3,910,281, proposes a suture having a surgical needle connectable to one end has an enlarged anchoring member secured to the other end thereof. A lateral projection is said to be provided on the anchoring member. It is proposed that the lateral projection be grasped by a physical instrument to position the anchor member during the suture tying procedure and a slit formed in the anchor member is said to releasably secure the suture to the anchor member for subsequent tensioning adjustments. Pierce, U.S. Patent No. 4,823,794, proposes a surgical pledget having a suture entrance slit extending through the pledget from a side wall to a central suture location within the pledget and means for retaining the suture at the suture location so that the pledget may be positioned on a medial portion of a suture.

The Examiner is of the view that, with respect to these grounds for rejection, that:

Kletschka teaches all limitations of preceding ... [independent] claim 1 as previously described, but fails to teach where the second outer edge of the second retaining member further comprises a fifth surface and a sixth surface that lie nominally perpendicular to the third surface of the second retaining member, and the holding means is an opening extending from the fifth or sixth surface to within the second retaining member, and where the opening further comprises an entrance and a rear surface and the width of the entrance is less than the width of the rear surface. Pierce teaches a suture anchor device wherein the retaining member (10) comprises a fifth surface and a sixth surface (32) that lie nominally perpendicular to surface (14) of the retaining member (10), and the holding means (24) is an opening extending from the fifth or sixth surface (32) to within the retaining member, and where the opening further comprises an entrance (28) and a rear surface (24) and the width of the entrance is less than the width of the rear surface (fig. 1) in order to secure the suture within the opening. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kletschka as taught by Pierce in order to further secure the suture within the opening.

As may be seen, the disclosure of Pierce, U.S. Patent No. 4,823,794, does not serve to remedy the deficiencies of Kletschka et al., U.S. Patent No. 3,910,281, since nowhere is a second retaining member having a third surface, a fourth surface, a fifth surface, a sixth surface and a second outer edge; where the third surface lies in a second plane and the ***fifth surface and the sixth surface lie nominally perpendicular to the second outer edge at their lines of intersection therewith*** or a holding means positioned within the second retaining member, the holding means comprised of an opening extending from the fifth or the sixth surface to within the second retaining member, fairly taught or suggested. This may be seen to overcome the 35 U.S.C. 103(a) rejection of previously presented dependent claim 6, now canceled, and claim 7 since the anchor device of Pierce does not include a fifth surface and a sixth surface that lie nominally

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perpendicular to the surface of the retaining member. In view thereof, it is respectfully requested that the grounds for rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Pierce, U.S. Patent No. 4,823,794, be removed.

The Examiner has rejected claim 5 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Wixey et al., U.S. Publication No. 2005/0096699. With respect to these grounds for rejection, the Examiner has taken the position that :

Kletschka teaches all limitations of preceding ... [independent] claim 1, but fails to teach where the holding means is a hook on the second retaining member. Wixey teaches a suture anchor wherein the holding means is a hook (370) to aid in securing the suture to the suture anchor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kletschka with a hook on the second retaining member as taught by Wixey in order to aid in securing the suture to the suture anchor.

While not agreeing with or acquiescing in the rejection, this rejection is nevertheless rendered moot by the cancellation of claim 5. In view thereof, it is respectfully requested that the grounds for rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Wixey et al., U.S. Publication No. 2005/0096699, be removed.

The Examiner has rejected claim 9 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Biggs et al., U.S. Patent No. 6,599,311. As indicated above, Kletschka et al., U.S. Patent No. 3,910,281, proposes a suture having a surgical needle connectable to one end has an enlarged anchoring member secured to the other end thereof. A lateral projection is said to be provided on the anchoring member. It is proposed that the lateral projection be grasped by a physical instrument to position the

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anchor member during the suture tying procedure and a slit formed in the anchor member is said to releasably secure the suture to the anchor member for subsequent tensioning adjustments. Biggs et al., U.S. Patent No. 6,599,311, proposes methods and assemblies for reducing the volume of a lung. Proposed are a plurality of anchors anchored at different positions in the lung. A cord is attached to each of the anchors. The anchors are drawn towards one another via the cords to cause the lung to collapse, compressing the tissue in the lung and establishing a reduction in lung volume.

With regard to these grounds for rejection, the Examiner has taken the position that:

Kletschka teaches all limitations of preceding ... [independent] claim 1 as previously described, but fails to teach each where the coupler is a helical member. Biggs teaches a suture anchor wherein the device is helical in order to aid in preventing movement of the suture along the anchor (Columns 20 and 22, proximate lines 35-40 and 30-38 respectively). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connector of Kletschka with a helical structure as taught by Biggs in order to aid in preventing movement of the suture along the anchor.

Contrary to the Examiner's position, nowhere is a second retaining member having a third surface, a fourth surface, a fifth surface, a sixth surface and a second outer edge; where the third surface lies in a second plane and the fifth surface and the sixth surface lie nominally perpendicular to the second outer edge at their lines of intersection therewith or a holding means positioned within the second retaining member, the holding means comprised of an opening extending from the fifth or the sixth surface to within the second retaining member, fairly taught or suggested. Even assuming, for the sake of argument, that sufficient motivation exists to combine the references did exist, the combination of references would not provide teaching sufficient to render applicants' claimed invention *prima facie* obvious. In view thereof, it is respectfully requested that the

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grounds for rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Biggs et al., U.S. Patent No. 6,599,311, be removed.

The Examiner has rejected claim 14 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Lyons et al., U.S. Publication No. 2004/0260344. As indicated above, Kletschka et al., U.S. Patent No. 3,910,281, proposes a suture having a surgical needle connectable to one end has an enlarged anchoring member secured to the other end thereof. A lateral projection is said to be provided on the anchoring member. It is proposed that the lateral projection be grasped by a physical instrument to position the anchor member during the suture tying procedure and a slit formed in the anchor member is said to releasably secure the suture to the anchor member for subsequent tensioning adjustments.

Lyons et al., U.S. Publication No. 2004/0260344, proposes a suture lock to be used with a suture thread. The suture lock is said to comprise at least one passageway for receiving a suture thread, with the passageway having at least a portion of its length having a longitudinal side opening arranged to slidably receive the suture. The passageway is tapered inwardly and including an interior surface having inwardly converging teeth. The invention may also comprise a suture lock having an adjustable channel located within the suture lock. The channel may be adjusted between an open and a closed position, thereby allowing the suture to be secured. Translation of the suture itself may be utilized to adjust the positioning of the channel. It is suggested that the suture lock could contain a releasable device to retain the channel in multiple positions between the closed and open position.

With regard to these grounds for rejection, the Examiner has taken the position that:

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Kletschka teaches a method of securing a suture used in a surgical procedure comprising the steps of: (a) locating a suture anchoring device (10e) in the proximity of a suture site, the suture anchoring device comprising: a first retaining member (24e) having a first surface, a second surface and a first outer edge; where the second surface lies in a first plane; the first retaining member having an opening (19e) that extends from the first outer edge to at least partially through the second surface to an inner point of the first retaining member; a second retaining member (18e) having a third surface, a fourth surface and a second outer edge; where the third surface lies in a second plane, the second retaining member having a holding means (19e); a coupler (23e) having a third outer edge and a cross-sectional area taken in a plane parallel to the first plane that is smaller than the cross-sectional area of the first retaining member taken in a plane parallel to the first plane; where the coupler joins the first retaining member to the second retaining member at the second surface and third surface; wherein the second and third surfaces are parallel to each other and non-coterminous (fig. 7); (c) wrapping the suture (11e) around the third outer edge of the coupler (23e); and (d) introducing the suture into the holding means (fig. 7). Kletschka fails to teach introducing the suture into said opening. Lyons teaches a suture anchor comprising an opening (36) and a holder (22), wherein the suture is introduced to both the introducer and the holder (fig. 10) in order to securely attach the suture to the anchor. It would have been an obvious to one of ordinary skill in the art at the time the invention was made to introduce the suture to the opening as well as the holder in order to aid in securing the suture to the anchor as taught by Lyons, since Kletschka has disclosed that the suture may be introduced to either the holder or the opening.

The applicants respectfully traverse this rejection on the grounds that, in order to have a suture site, ***the act of suturing must have been completed***. The present invention requires that the suture anchoring device be located in the proximity of a suture site ***prior to introducing the suture into the opening of the first retaining member***. In contradistinction therewith, the suture lock proposed by Lyons requires that the suture be introduced into an opening (36) prior to suturing, and therefore, prior to locating the suture lock in the proximity of a suture site. As such, the combination of Kletschka et al., in view of Lyons et al., cannot serve to render applicants' claimed invention prima facie obvious.



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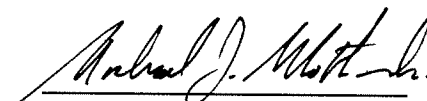
As is well settled, "the mere fact that the reference could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." In re Gordon, at 221 USPQ 1127, 733 F.2d 902. It is submitted that the lack of technical motivation for making the modifications necessary to arrive at applicants' claimed invention is evidence that the suggestion for the modification could not have come from the references themselves. In view thereof, it is respectfully requested that the grounds for rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Kletschka et al., U.S. Patent No. 3,910,281, in view of Lyons et al., U.S. Publication No. 2004/0260344, be removed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(13792).

In view of the foregoing, it is respectfully submitted that the present claims re in condition for allowance. Prompt notification of allowance is respectfully solicited.

Respectfully submitted,

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